

## Actavis and Error Costs: A Reply to Critics

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Any two principal competitors (call them the “Brand” and the “Generic”) can profit by agreeing not to compete with each other, so long as they can find a way to split the extra profits. The longer they avoid competition, the more profits they can split.

A settlement of a Hatch-Waxman patent suit provides the perfect venue for such an agreement. The Brand and the Generic have a joint incentive to settle the suit to avoid competition for as long as they can. It does not matter whether the Generic is probably not infringing or the patent is likely invalid; these factors only suggest that the Generic will demand a larger payment from the Brand. The longer the Generic agrees to stay out in exchange for a payment—a “reverse” payment, in the Supreme Court’s terminology, because the patentee rather than the alleged infringer makes the payment—the greater the joint profits and the more the Brand must pay. These incentives are the elephant in the room in *FTC v. Actavis*,<sup>1</sup> and the basis for the Court’s judgment that such settlements are subject to antitrust scrutiny. They must always be kept front of mind.

We argued in our article *Activating Actavis* that the Court’s opinion laid out a practical and economically sensible approach to evaluating the legality of these settlements.<sup>2</sup> Because payments are observable<sup>3</sup> and because lost competition is not, the Court concluded that a court or jury should rely heavily on the size of a reverse payment as a “surrogate” for patent-case weakness and therefore for lost competition.<sup>4</sup> Payment size is likewise a proxy for market power.<sup>5</sup>

In our article, we argued that a plaintiff’s demonstration of a net payment in excess of avoided litigation cost, combined with limitations on the Generic’s ability to compete, satisfies the plaintiff’s burden of production in a rule-of-reason case.<sup>6</sup> We call this the “*Actavis* inference.” This inference is established whether the payment is made in cash or by some other form of value transfer.<sup>7</sup> A large

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<sup>1</sup> *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

<sup>2</sup> Aaron Edlin, Scott Hemphill, Herbert Hovenkamp & Carl Shapiro, *Activating Actavis*, ANTITRUST, Fall 2013, at 16 [hereinafter Edlin et al., *Activating Actavis*].

<sup>3</sup> In some instances, the valuation of this consideration is an intricate proposition. For a discussion of this point, see *id.* at 18. Payment as an economic matter must include not only cash but any consideration, including the Brand’s promise not to launch an authorized generic.

<sup>4</sup> *Actavis*, 133 S. Ct. at 2236–37.

<sup>5</sup> *Id.* at 2236 (“[T]he size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power . . . .”) (internal quotation omitted).

<sup>6</sup> Edlin et al., *Activating Actavis*, *supra* note 2, at 18.

<sup>7</sup> The competitive, business, and economic effects of cash and in-kind payments are identical so it seems evident to us that they should be treated identically. Compare *In re Niaspan Antitrust Litig.*, No. 13-MD-2460, 2014 WL 4403848, at \*11 (E.D. Pa. Sept. 5, 2014) (“[T]he term ‘reverse payment’ is not limited to a cash payment.”), *In re Lipitor Antitrust Litig.*, No. 3:12-cv-2389 (PGS), 2013 WL 4780496, at \*26 (D.N.J. Sept. 5, 2013) (“[N]othing in *Actavis* strictly requires that the payment be in the form of money . . . .”), and *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 392 (D. Mass. 2013) (“Nowhere in *Actavis* did the Supreme Court explicitly require some sort of monetary transaction . . . .”), with *In re Loestrin 24 Fe Antitrust Litig.*, No. 1:13-md-2472-S-PAS, 2014 WL 4368924, at \*12 (D.R.I. Sept. 4, 2014) (concluding that payment must be in cash based on “literal holding of *Actavis*,” while noting the resulting “quandary” that under this interpretation, settling parties “are likely to evade Sherman Act scrutiny”) and *In re Lamictal Direct Purchaser Antitrust Litig.*, No. 12-cv-995 (WHW), 2014 WL 282755, at \*5 (D.N.J. Jan. 24, 2014) (reading *Actavis* to require that the settlement “must include money”). See also *In re Wellbutrin XL Antitrust Litig.*, No. 2:08-cv-02431-MAM, at \*4 (E.D. Pa. Jan. 17, 2014) (deferring consideration of the question).

Brand payment, as part of an agreement with delayed Generic entry, is not irrefutable evidence of an anticompetitive settlement agreement, but it does leave the defendants with some explaining to do.

The *Actavis* inference finds ample support in both case law and economic analysis. The inference follows directly from the Court's opinion, which states, for example, that "a court, by examining the size of the payment, may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent . . . ." <sup>8</sup> The inference is also supported by the straightforward economic model that we offered in *Activating Actavis*; our model exposed the basic incentive to delay competition identified by the Court and the correspondence between the size of a reverse payment and the reasonable inference of delay.

Our analysis has been challenged by four economists, Barry Harris, Kevin Murphy, Robert Willig, and Matthew Wright (HMWW).<sup>9</sup> HMWW have two central claims: (1) that our proposal is contrary to *Actavis* because it conflicts with the Court's refusal to adopt a particular "quick-look" approach and (2) that our proposed interpretation condemns procompetitive agreements. HMWW offer a theoretical example in support of their second claim.

In this reply, we explain why HMWW are mistaken on both points. Without the *Actavis* inference, it would be very hard for a plaintiff to prove that there has been payment for delay, and in turn it likely would be that the Brand would pay for delay. In other words, once one fully takes into account the parties' joint incentives to delay generic entry, even in HMWW's theoretical example, the *Actavis* inference will, in practice, lead to more competitive outcomes than would arise without it. The approach we favor prevents many false negatives that would occur if courts could not infer delayed competition from payment size. Our approach also will produce few false positives, contrary to the implication of HMWW's critique.

### The *Actavis* Inference Is Legally Sound

HMWW first attack the *Actavis* inference on essentially legal grounds, asserting that we "ignore the language of the *Actavis* opinion that expressly rejects the 'quick-look' approach and finds that many factors need to be considered in a rule-of-reason analysis of reverse payments."<sup>10</sup> We disagree. In fact, as detailed in our earlier article, the *Actavis* inference is rooted in a close reading of the case.

HMWW are correct that the Court rejected a particular quick-look approach. That approach would have limited the plaintiff's burden to establishing a gross payment to the generic and delayed generic entry, and sharply limited the defendants' permitted responses. But HMWW overstate the implications of that rejection. Our interpretation of *Actavis* differs from the rejected quick-look rule in two respects.

First, our interpretation expands the plaintiff's burden. The rejected approach relieved plaintiffs from the burden of establishing a large net payment to the Generic; instead, plaintiffs only would have needed to show that the Brand made a gross payment. Defendants would have then borne the burden of arguing that the payment was no larger than avoided litigation cost, or was made

<sup>8</sup> *Actavis*, 133 S. Ct. at 2237.

<sup>9</sup> Barry C. Harris, Kevin M. Murphy, Robert D. Willig & Matthew B. Wright, *Activating Actavis: A More Complete Story*, ANTITRUST, Spring 2014, at 83 [hereinafter HMWW].

<sup>10</sup> *Id.*

Without the *Actavis* inference, it would be very hard for a plaintiff to prove that there has been payment for delay, and in turn it likely would be that the Brand would pay for delay.

in exchange for Generic services rather than delay.<sup>11</sup> Under our approach, the plaintiff bears the burden on these points. This is how we read *Actavis*.

More precisely, we propose that the plaintiff bear the burden of production as to avoided litigation expense and the burden of persuasion overall. As to the value of services rendered by the Generic, we suggest that a court place the burden of production on defendants because they have better information about that. Our attention to avoided litigation expense and the value of Generic services again corresponds to the emphasis placed on these points by the Court: “Where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement.”<sup>12</sup>

Second, our approach also differs from a quick look by permitting the defendant to offer a wider range of responses. In a quick look, defendants may present evidence that the restraint is in fact, on balance, procompetitive.<sup>13</sup> But quick-look cases are truncated, in that they deprive defendants of the opportunity to challenge the initial inference of an anticompetitive effect by, for example, presenting evidence that market power is lacking. In contrast, our ordinary rule-of-reason procedure leaves defendants free to present contrary evidence that challenges the inference of anticompetitive effect.

The rejection of a quick look, however, does not mean that the plaintiff must show directly that the settlement led to later entry than that expected in litigation. Such a direct showing would require litigating the patent, a trial by ordeal that the Court explicitly says is unnecessary if a sufficiently sizable reverse payment exists. Rejection of a quick-look approach alters the applicable procedure, but the Court makes clear that even under its rule-of-reason approach, the Court will accept the use of surrogates or shortcuts, provided that they are reasonable to the situation at hand. Even under the rule of reason, the parties need not “present every possible supporting fact or refute every possible pro-defense theory.”<sup>14</sup> Rather, there is a “sliding scale in appraising reasonableness.”<sup>15</sup>

It bears repeating that the *Actavis* inference does not preclude antitrust defendants from rebutting the prima facie case or otherwise presenting a defense. Similar inferences have been a part of antitrust law for more than 50 years. For example, in merger cases, a presumption of illegality may be established based on information about the number of firms in a relevant market and their market shares. The merging parties can then rebut this inference.<sup>16</sup>

The Court emphasizes the reverse payment’s size as the key to understanding the settling parties’ likely motivations and the settlement’s potential anticompetitive effects. A key question under the rule of reason is always what evidence creates a sufficient inference of “likely anticompetitive effects,” thereby shifting the burden to the defendant. Another critical question is what justifica-

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<sup>11</sup> See Brief for the Petitioner at 17, *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013) (No. 12-416) (“The principal means of rebuttal would be through proof that the payment was instead consideration for unrelated property or services, or that the payment was commensurate with the litigation costs that the brand-name manufacturer would otherwise have borne.”); *id.* at 37–39 (elaborating this approach).

<sup>12</sup> *Actavis*, 133 S. Ct. at 2236.

<sup>13</sup> *Id.* at 2237 (“‘Quick-look analysis in effect’ shifts to ‘a defendant the burden to show empirical evidence of procompetitive effects . . . .’”) (quoting *Cal. Dental Ass’n. v. FTC*, 526 U.S. 756, 775 n.12 (1999)).

<sup>14</sup> *Id.* at 2237.

<sup>15</sup> *Id.* (internal quotation marks omitted).

<sup>16</sup> See, e.g., *United States v. Phila. Nat’l Bank*, 374 U.S. 322, 363–64 (1963); *United States v. Bazaarvoice, Inc.*, No. 13–cv–00133–WHO, 2014 WL 203966, at \*64 (N.D. Cal. Jan. 8, 2014).

tions the courts will admit to rebut the inference. It is clear from both our analysis and from the Court's opinion that a large reverse payment creates such an inference. The threshold for sufficient "largeness" suggested by both the Court and our economic logic is the sum of likely avoided litigation costs and the reasonable value of any other consideration provided by the Generic, such as services.

The Court's repeated use of the terms "unexplained" or "unjustified" to modify "large reverse payments" suggests that such payments are not illegal if appropriately justified, *and* that the burden is on the defendant to justify (i.e., explain) them. The Court writes that "[a]n antitrust defendant may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason."<sup>17</sup> The Court concludes that "[i]n sum, a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects; one who makes such a payment may be unable to explain and to justify it . . . ."<sup>18</sup> Allocating the burden to the defendant to provide justifications for a settlement also makes sense: it would be unreasonable and inefficient to expect a plaintiff to prove the absence of any convincing justification without requiring the defendants first to narrow the scope of the facts and justifications at issue by making their case.

### The *Actavis* Inference Accommodates Procompetitive Settlements

We now turn to HMWW's central claim: that our rule would sometimes condemn procompetitive settlements. Our reply to this claim is that once one accounts for the parties' clear incentive to delay generic entry, false negatives would abound under the HMWW rule, while false positives will be exceedingly rare under our rule.

We define a settlement in a reverse payment case as anticompetitive if consumers are worse off under the settlement than they would be under one of two benchmarks: (1) the outcome of litigation, in expectation; or (2) an alternative settlement that did not include a large payment. A settlement is anticompetitive if competition is delayed in comparison to *either* benchmark. *Actavis* supports this approach. There, the Court points out that if antitrust law prohibits the parties from settling with a large reverse settlement, they can (typically) settle without one, and with an earlier entry date.<sup>19</sup> The *Actavis* dissent criticizes the Court for not explaining why a better settlement will ordinarily exist, but acknowledges and apparently accepts this standard.<sup>20</sup> Consistent with our definition of anticompetitive settlements, HMWW write that a reverse payment benefits consumers if it: "(1) causes the Brand to be willing to accept a settlement permitting entry on a date earlier than the expected entry date under litigation; and (2) results in a settlement that would not have occurred without a reverse payment."<sup>21</sup>

HMWW criticize the model that we propose because it assumes risk neutrality and is therefore a special case. But, as we shall explain, the *Actavis* inference remains valid in much broader cir-

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<sup>17</sup> *Actavis*, 133 S. Ct. at 2236.

<sup>18</sup> *Id.* at 2237.

<sup>19</sup> *Id.* The Court noted: "[T]he fact that a large, unjustified reverse payment risks antitrust liability does not prevent litigating parties from settling their lawsuit. They may, as in other industries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point." *Id.*

<sup>20</sup> See *id.* at 2247 (Roberts, C.J., dissenting) ("The majority assures us, with no support, that everything will be okay because the parties can settle by simply negotiating an earlier entry date for the generic drug manufacturer, rather than settling with money.").

<sup>21</sup> HMWW, *supra* note 9, at 83.

cumstances, and the HMWW possibility of a procompetitive settlement is based on quite a special case. Indeed, considering false negatives as well as false positives, our approach yields greater accuracy than HMWW's preferred approach.

HMWW's first example of a "procompetitive" settlement actually involves payment for delay. In that example, the patent has 100 months left.<sup>22</sup> A risk-averse Brand has a 70 percent chance of winning its suit against a Generic so the expected date of entry under litigation is 70 months. Nonetheless the Brand pays the defendant a large reverse payment and agrees to an earlier entry date than expected under litigation—say 50 months—in order to get a certain outcome and avoid bearing the risk cost from an uncertain litigation outcome. HMWW argue that when our model is extended to include Brand risk aversion, such settlements with large reverse payments and early entry dates are possible.<sup>23</sup> We agree with them that it is theoretically possible that a sufficiently risk-averse Brand might (if necessary) be willing to make a high payment *and* at the same time settle for an entry date that occurs before the expected date under litigation.<sup>24</sup> (In *Activating Actavis*, we concluded that the Court did not wish to entertain arguments, such as this one, that rely on Brand risk aversion. Here we discuss the appropriate approach if, contrary to that conclusion, such arguments are permitted.)

The first problem with this HMWW example is that this hypothetical settlement is actually *not* procompetitive under the dual benchmark standard that all members of the Court accept, and which HMWW also appear to adopt. If the large and unexplained payment is prohibited under antitrust law, then the parties have a strong incentive to reach an alternative settlement with an earlier entry date and no large reverse payment. Compared with this alternative settlement, the proposed "procompetitive" settlement is actually anticompetitive, as it involves a payment made to delay the start of competition. HMWW presumably appreciate this feature of their example, but they downplay it.

The second problem with this HMWW example is that the parties would not choose this hypothetical settlement. Their settlement is simply not an equilibrium outcome in their own model. If the parties are free to choose among what HMWW call "procompetitive" settlements (all legal under HMWW's approach), the parties will have a strong incentive to choose an entry date very close to the expected entry date under litigation. Better yet for the parties, if they can get away with it, they would settle upon an even later entry date. We very much doubt such settlements would be deterred if antitrust law took the lenient HMWW approach to patent settlements, because although such settlements might be illegal even in HMWW's preferred legal regime, plaintiffs would find it difficult to prove that the settlement entry date came later than the expected date without an *Actavis* inference.

Figure 1 illustrates why the Brand and Generic would not pick the hypothetical "procompetitive" settlement that HMWW propose. Figure 1 is based on Figures 2 and 3 in HMWW's article. In our Figure 1, the point *S* represents what HMWW call a procompetitive settlement where the *Actavis* inference would yield a false positive (any point on the supposedly procompetitive segment in

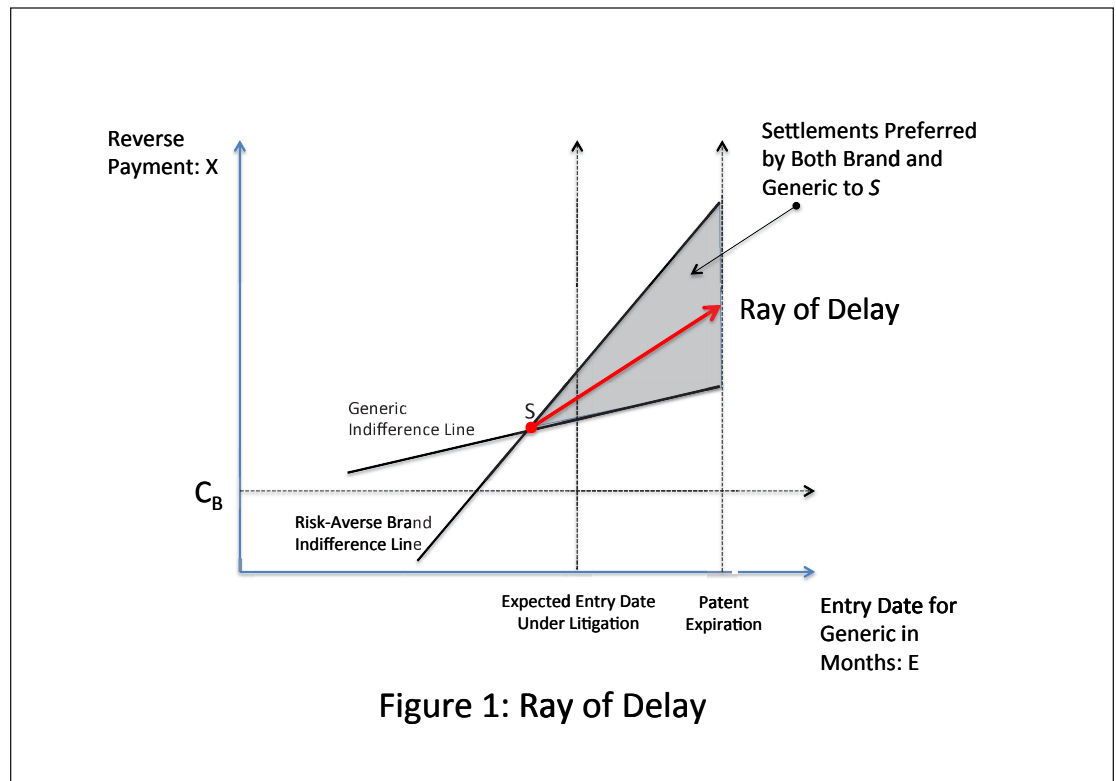
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<sup>22</sup> We refer here to their example, *id.* at 85–86, in the section titled "The EHHS Result Does Not Always Hold When Other Factors Are Considered."

<sup>23</sup> See *id.* at 85–86 & fig. 2.

<sup>24</sup> For purposes of this reply, we adopt HMWW's assumptions that the Brand is risk averse and the Generic is risk neutral, see *id.* at 85 & n.18, as well as HMWW's implicit assumption that the Brand lacks substantial bargaining power in settlement negotiations. If the Generic is sufficiently risk averse, or the Brand has substantial bargaining power, it is likely that the Brand will not need to make a high payment to the Generic, except to gain an entry date later than the expected entry date under litigation.

*The parties' incentive is to delay entry and split the extra profits . . .*



HMWW Figure 2 or in the shaded area in HMWW Figure 3). Under the settlement  $S$ , the reverse payment  $X$  exceeds the Brand's avoided litigation costs  $C_B$ , and the entry date for the Generic is earlier than the expected entry date under litigation.

We now demonstrate that the Brand and Generic will not agree to settle at point  $S$ . The steeper line through  $S$  represents settlements that the Brand considers equally attractive to  $S$ . The flatter line through  $S$  represents settlements that the Generic considers equally attractive to  $S$ . The Generic's indifference line is flatter than the Brand's due to the fundamental incentive that, as we noted, should always be front of mind: delaying entry is more valuable to the Brand (because it prolongs monopoly profits) than the cost to the Generic, which only loses a share of profits under competition. All points northeast of  $S$  between these two lines, as shown by the shaded area in Figure 1, are preferred by *both* the Brand and the Generic to  $S$ .

The parties' incentive is to delay entry and split the extra profits, moving their settlement into the shaded area in Figure 1. Just which alternative settlement they will pick depends on how they split the joint gains from delayed entry by the Generic. If the gains are split equally, the parties will have an incentive to move out along the Ray of Delay depicted in Figure 1. With unequal bargaining power, the Ray of Delay would rotate up or down, but regardless of the ray's slope, the parties will seek to move out along the ray. As the parties move out along the Ray of Delay, the Brand pays ever larger amounts for ever more delay. The parties have an incentive to push out as far as they can along the Ray of Delay, up to patent expiration, limited only by antitrust risk. HMWW do not dispute this fact. The incentive to move out the Ray of Delay is the elephant in the room of reverse payment cases, one that should not be forgotten.

How would the courts evaluate such settlements to make sure that they toe the line, according to HMWW? As we understand their approach, an antitrust plaintiff would need to present direct evidence that the Brand had, in their example, no more than a 70 percent chance of winning the patent suit. This direct approach to evaluating the settlement, without the benefit of an inference

from a large unexplained payment, would be very difficult to reliably implement. It would be virtually impossible without litigating the patent, which the Court said should “normally” not be necessary.<sup>25</sup> A major drawback to the HMWW approach is its inconsistency with *Actavis*, which emphasizes the inference of harm to competition that can be drawn from a large unexplained payment. Another drawback is that plaintiffs would find it very difficult in practice to prove directly that a payment was for delay, so HMWW are inviting many false negatives if the large reverse payment cannot be used to infer anticompetitive effects.

HMWW also offer a second example, carefully constructed to preclude the possibility of a voluntary settlement with a reverse payment below the Brand’s avoided litigation cost.<sup>26</sup> Unlike their first example, this example creates a settlement region that is procompetitive under the dual benchmark standard. However, the assumptions underlying this example are quite particular. This region can exist only if the Brand is risk averse and, simultaneously, the Generic is unreasonably optimistic in its expectations of success at trial in the patent suit. It will be a challenge for courts to determine *ex post* what the *ex ante* beliefs of the Brand and Generic were, but let’s assume, nonetheless, that courts can somehow know whose *ex ante* expectations are reasonable.

*[T]he greatest problem is the false negatives that will dominate in practice if plaintiffs do not have a practical way to try these cases.*

We agree—assuming that risk aversion defenses are allowed at all—that if the defendants could prove they were in this region, they would have found the “convincing justification” that the Court spoke of for a large reverse payment.<sup>27</sup> But the possibility of such a region does not justify eliminating the inference that we propose within a standard rule-of-reason framework.<sup>28</sup> As explained above, without the *Actavis* inference, there would be many false negatives, as antitrust plaintiffs struggled in every case to compare the settlement to a reconstructed measure of the expected litigation outcome.

Moreover, our point about the frequency of significant false positives under the *Actavis* inference is fundamental and applies equally to HMWW’s second example. As with their first example, their proposed procompetitive settlement is not an equilibrium because the defendants will always seek to delay entry (moving out along the Ray of Delay) for as long as they can get away with, and split the resulting monopoly profits. The point here is that switching to HMWW’s preferred legal regime would not yield many of the procompetitive settlements that they say should motivate their regime. Parties will instead be free to follow their incentives to delay. As a result, the greatest problem is not the false positives that concern HMWW. Rather, the greatest problem is the false *negatives* that will dominate in practice if plaintiffs do not have a practical way to try these cases.

## Conclusion

A practical approach is to allow the plaintiff an inference of anticompetitive effect if the plaintiff shows that a large reverse payment has been made and entry has been restricted. The theoretical possibility of false positives under the *Actavis* inference does not make it a bad rule. We must ask how many false positives are produced by the inference; how many remain once the inference is supplemented by defendants’ opportunity to demonstrate that their settlement is in fact procompetitive; and how many false negatives are avoided, all compared to an alternative method of establishing liability.

<sup>25</sup> *Actavis*, 133 S. Ct. at 2236 (“[I]t is normally not necessary to litigate patent validity to answer the antitrust question . . .”).

<sup>26</sup> HMWW, *supra* note 9, at 86–87 & fig. 3, in the section titled “Reverse Payments May Permit Settlements that Enhance Consumer Welfare.”

<sup>27</sup> See *Actavis*, 133 S. Ct. at 2237.

<sup>28</sup> See, e.g., Einer Elhauge & Alex Krueger, *Solving the Patent Settlement Puzzle*, 91 TEX. L. REV. 283 (2012) (considering risk aversion and asymmetric expectations and reaching a similar result).

The HMWW false positives can only arise under special circumstances. Moreover, without the *Actavis* inference, even in these special circumstances the parties would not actually choose a procompetitive settlement. The *Actavis* inference may lead to litigation costs in these special circumstances, as defendants are put to the trouble of explaining their unusual circumstances. But it avoids the alternative, which would be highly anticompetitive settlements and many false negatives. When both false positives and false negatives are considered, and when we consider the settlements that the Brand and Generic would actually choose without the *Actavis* inference, it becomes clear that the inference is a very good idea. ●